5 510(k) Summary

5.1 Submitter's Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: 1-978-747-2509

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Contact Person: Jennifer M. Jackson, MS

Date of Submission: 20-Feb-2014

5.2 Name of the Device

Trade Name: Straumann® Variobase™ Abutments

Common Name: Dental Implant Abutment

Classification Name: Abutment, Implant, Dental, Endosseous

Regulation Number: §872.3630

5.3 Predicate Device(s)

- K120822, Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC (Institut Straumann AG)
- K111935, Ti-Base Abutment (NT-Trading GmbH & Co. KG)

5.4 Device Description

The Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments, sometimes referred to as "Ti-bases". Straumann® Variobase™ Abutments are available to fit Straumann® dental implant platforms NNC (Narrow Neck CrossFit®), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit®), and RC (Regular CrossFit®). A dental laboratory technician would design the corresponding coping and/or crown (the second component of the Variobase two-piece abutment) and/or prosthetic restoration in the

dental laboratory using either a burnout coping or STL model for open CAD software. The coping and/or crown would be manufactured via validated Straumann milling.

5.5 Intended Use

Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments intended to be placed onto Straumann dental implants to provide support for customized prosthetic restorations such as crowns and bridges. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

5.6 Technological Characteristics

Straumann® Variobase™ Abutments are two-piece abutments consisting of a pre-manufactured (stock) abutment made from a titanium-aluminum-niobium alloy and a coping and/or crown which is designed in the dental laboratory by a dental technician using open CAD software and manufactured via validated Straumann milling.

The Ti-base components of the Straumann® Variobase™ Abutments are identical to the Ti-base components of the Straumann predicate (K120822). The Ti-base components are also equivalent to the Ti-base components identified in K111935.

The materials which may be used to manufacture the coping/crown component of the Straumann® Variobase™ Abutments are identical to the identified predicate devices and include:

Milling: Polycon® ae (temporary restorations – K120822)

Zerion® (K120822)

5.7 Performance Testing

The material used in the manufacture of Straumann® Variobase™ Abutments is a titanium-aluminum-niobium alloy which meets the requirements of ISO 5832-11. Bench testing was performed with Polycon® ae and Zerion® to evaluate the fatigue load limits of the proposed Straumann® Variobase™ Abutments. Dynamic fatigue tests were conducted in according to the FDA guidance document *"Guidance for Industry and FDA*

Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments".

5.8 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® Variobase™ Abutments are substantially equivalent to the predicate devices and do not pose new issues of safety and effectiveness when used as labeled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Straumann USA, Limited Liability Company
Jennifer M. Jackson, MS
60 Minuteman Road
Andover, MA 01810

Re: K132219
Trade/Device Name: Straumann® Variobase ™Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Abutment, Implant, Dental, Endosseous
Regulatory Class: II
Product Code: NHA
Dated: January 23, 2014
Received: January 24, 2014

Dear Ms. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132219

Device Name: Straumann® Variobase™ Abutments

Indications for Use:

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S